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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,981	10/31/2003	Sheryl E. Siegel	200.1162US	8850

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DAVIDSON, DAVIDSON & KAPPEL, LLC
14th Floor
485 Seventh Avenue
New York, NY 10018

EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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08/09/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/698,981	Applicant(s) SIEGEL, SHERYL E.	
	Examiner MICAH-PAUL YOUNG	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,6,74-80,82,84,86,88,90-95,97 and 98 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 3,6,74-80,82,84,86,88,90-95,97 and 98 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 4/19/10.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 6, 75, 78, 84, 91, 92, 94, 95, 97 and 98 are rejected under 35 U.S.C. 102(b) as being anticipated by Motoyama et al (USPN 4,154,636 hereafter ‘636).

The ‘636 patent teaches a method for providing the identification of a dosage form comprising imparting a scent to the dosage form in the form of an orange essence to a film coating layer for a capsule (Example 3). The orange essence imparts an orange flavor and smells to the capsule, and would provide a way to identify the dosage form from others (Examples). The scent is sequestered to the film coating (Example). The dosage form is a capsule or plane tablet that is coated with a sustained release film (col. 3, lin. 30-40). The film comprises cellulose acetate a polymer that delays the release of the core medicine (col. 2, lin. 55-60). The amount of orange essence is sufficient to be detected by a human, and by extension a non human animal with a higher olfactory sense such as a canine or an electronic olfactory device. The medicament is administered to a human for consumption and thus the active medicament must be capable of administration and sanctioned by a government agency for such administration. These disclosures render the claims anticipated.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 6, 74-80, 82, 84, 86, 88, 90-95, 97 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Motoyama et al (USPN 4,154,636 hereafter '636) in view of Cuca et al (USPN 5,494,681 hereafter '681) and Balestrieri et al (USPN 5,409,839 hereafter '839).

As discussed above the '636 patent discloses a method of identifying a pharmaceutical dosage form by imparting a scent to a sustained release tablet or capsule by imparting the scent to a film coating. The tablet can be identified by the orange scent. The reference differs from the instant claims in that it is silent to the specific active agent in the tablet or capsule. The inclusion of a scent to an opioid capsule or tablet is well known in the art as seen in the '681 patent.

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The '681 patent discloses a tasteless drug dosage form comprising opioids such as codeine and morphine (col. 3, lin. 29-31). The dosage form can be a capsule (col. 6, lin. 55-65). The dosage form comprises essential oils and synthetic oils such as peppermint, spearmint, and fruit oils such as orange, lemon and grape (col. 7, lin. 1-15). It would have been obvious to include the opioids of the '681 patent into the formulation of the '636 patent since both formulations provide similar capsules with flavor oils in the coating.

The combination differs from the instantly claimed method in that it does not provide a separate electronic device for detecting the scent in the pharmaceutical dosage form. The use of an electronic device to detect an imparted scent or tagging compound is known in the art as seen in the '839 patent.

The '839 patent discloses a method of tagging and detecting tracer molecules on drugs (abstract). The method comprises imparting a concentration of perfluorocarbon tracer (PFT) compounds to a drug formulation, where the PFT is below the threshold of human detection (col. 4, lin. 30-45). The PFT compounds can be microencapsulated and sequestered depending on the application (col. 5, lin. 26-38). The tagged compounds are detected remotely via a separate electronic device (col. 5, lin. 50-col. 6, lin. 38). It would have been obvious to impart these PFT compounds to the opioid formulation of the '681 in order to track their movement remotely.

With these aspects in mind it would have been obvious to impart the scents and tagging compounds of the '839 patent to the coated opioid compositions of the '681 patent in order to track the opioid remotely and identify the source of the compositions. It would have been obvious to follow the suggestions of the '681 patent and taste mask the opioid by including a flavor and scented coating as seen in the '636 patent in order to identify the composition. This

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combination would have been obvious since both patents disclose coated medicaments with impermeable or semi-permeable coatings, surrounding dosage core comprising medicaments.

One of ordinary skill in the art would have been motivated tag the opioid composition with either the scent of the '636 or other PFT compounds of the '839 patent in order to track and later identify the dosage forms safely and remotely.

Response to Arguments

Applicant's arguments, see Remarks, filed 4/19/10, with respect to the rejection(s) of claim(s) 3, 6, 74-80, 82, 84, 86, 88, 90-95, 97 and 98 under 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the preceeding prior art rejections.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAHA-PAUL YOUNG/
Examiner, Art Unit 1618